NDA 50-638/S-006

JUL 20 1999

Baxter Healthcare Corporation
Attention: Ms. Marcia Marconi
Vice President, Regulatory Affairs
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated June 3, 1999, received June 7, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Penicillin G Potassium Injection in Plastic Container, PL 2040.

This supplemental new drug application provides for removal of recommendations by the American Heart Association and the American Dental Association for the use of antibiotics as prophylaxis of bacterial endocarditis in product labeling. The following changes are noted in the package insert:

- The **INDICATIONS AND USAGE, Prophylaxis** subsection has been deleted.
- The **DOSAGE AND ADMINISTRATION, Prophylaxis** subsection has been deleted.
- In the **REFERENCES** section, Reference No. "4" has been deleted, and the Reference No. "5" has been renumbered to "4."

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling (package insert submitted June 3, 1999) with the revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

In the PRECAUTIONS, Laboratory Studies subsection, last sentence, please change the superscript after "See CDC recommendations." from "5" to "4" as a result of the references being renumbered in the **REFERENCES** section.

This revision is a term of the approval.

Also, we remind you that these labeling changes may apply to any additional penicillin product not listed in this letter.

Furthermore, the changes approved in this supplement must be implemented within three months from the date of this letter. If you do not implement the above changes within three months, this

drug product may be considered misbranded.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-638/S-006." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Mr. Stephen T. Trostle, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research